

PATENT COOPERATION TREATY

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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RUTGER 0004	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/36292	International filing date (day/month/year) 13 November 2003 (13.11.2003)	Priority date (day/month/year) 13 November 2002 (13.11.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): C07K 14/00 and US Cl.: 435/69.7			
Applicant RUTGERS, THE STATE UNIVERSITY			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>1</u> sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 01 October 2004 (01.10.2004)		Date of completion of this report 10 May 2005 (10.05.2005)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer <i>[Signature]</i> A.R. Salimi Telephone No. (571) 272-1600	

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed.
- ☒ the description:
pages 1-74 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the claims:
pages 76-79 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages 75 filed with the letter of 28 January 2005 (28.01.2005)
- ☒ the drawings:
pages 1-11 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 5-7,10 and 13-42

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 5-7,10 and 13-42

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-4, 8, 9, 11, 12</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-4, 8, 9, 11, 12</u>	NO
Industrial Applicability (IA)	Claims <u>1-4, 8, 9, 11, 12</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-4, 8, 9, 11 and 12 lack inventive step under PCT Article 33(3) as being obvious over Wang et al. (Virology, 1996, Vol. 223, pp 41-50).

The above cited reference taught NS1 domain of influenza A and it's binding to dsRNA (see the abstract). In addition, they taught labeled fusion protein to NS1 (see page 42, right column, last full paragraph)

The newly amended claims filed (28 January 2005) have added limitations of "dsRNA of about 16 base pairs in length", to overcome the lack of novelty over the teaching of Wang et al. WANG et al taught a 55 base pair dsRNA (see page 44). However, the invention as a whole is prima facie obvious, because the Applicants' own disclosure on page 21, lines 28 to 29 asserts "the Length and ribonucleotide sequence of the dsRNA are not critical". Applicants go on to assert that the invention may be conducted using short synthetic dsRNA. Thus, one of ordinary skill in the art at the time of filing would have been motivated by teaching of WANG et al to utilize the binding assay for drug discovery. Especially given Applicants' won admission in the disclosure that the size of the dsRNA is not critical. Therefore, given the teaching of the prior art one of ordinary skill in the art at the time of filing would not have anticipated any unexpected results. The authority cannot find any unexpected results in the disclosure.

Claims 1-4, 8, 9, 11 and 12 lack an inventive step under PCT Article 33(3) as being obvious over LU et al. (Virology, 1995, Vol. 214, pages 222-228).

The above-cited reference taught NS1 binding to dsRNA (see the abstract). In addition, they taught labeled fusion protein to NS1 (see Figure 1).

The newly amended claims filed (28 January 2005) have added limitations of "dsRNA of about 16 base pairs in length", to overcome the lack of novelty over the teaching of LU et al. LU et al taught a 29 base pair dsRNA (see page 223). However, the invention as a whole is prima facie obvious, because the Applicants' own disclosure on page 21, lines 28 to 29 asserts "the Length and ribonucleotide sequence of the dsRNA are not critical". Applicants go on to assert that the invention may be conducted using short synthetic dsRNA. Thus, one of ordinary skill in the art at the time of filing would have been motivated by teaching of LU et al to utilize the binding assay for drug discovery. Especially given Applicants' own admission in the disclosure that the size of the dsRNA is not critical. Therefore, given the teaching of the prior art one of ordinary skill in the art at the time of filing would not have anticipated any unexpected results. The authority cannot find any unexpected results in the disclosure.

Claims 1-4, 8, 9, 11, 12 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NEW CITATIONS

NONE